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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,969	09/11/2003	Wael R. Joseph	KCC 4979.1 (K-C 19,378B)	5031

321 7590 03/12/2007

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
AHMED, HASAN SYED	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/12/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary	Application No.	Applicant(s)	
	10/659,969	JOSEPH ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33 and 35-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33 and 35-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/5/06 11/2/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants': (1) amendment/remarks, which were filed on 21 December 2006; and (2) Information Disclosure Statements, which were filed on 5 October 2006 and 2 November 2006.
- The amendment filed on 21 December 2006 has been entered
- Objections to claim 25 and the specification are hereby withdrawn in light of the amendment.
- Currently pending claims 1-33 and 35-61 remain rejected under 35 USC 103 and 112(1), and obviousness-type double patenting.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the specification does not teach how to use glucosylceramide, *i.e.*, no amounts, weights, or percentages are given; no mention is made as to how the glucosylceramide is effectively incorporated into the tissue product claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23, 25-56, and 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vega, *et. al.* (U.S. Patent No. 6,153,209).

Vega, *et. al.* teach an absorbent product (*see* col. 1, line 7). The absorbent product disclosed is comprised of:

- the moisturizing and lubricating compositions of instant claims 1 and 32 (*see* col. 25, line 65 – col. 26, line 14);
- the emollient of instant claim 1 (*see* col. 15, line 26);
- the humectant of instant claims 1 and 32 (*see* col. 25, line 65 – col. 26, line 14);
- the immobilizing agent of instant claims 1 and 32 (*see* col. 26, line 6);
- the compatibilizing agent of instant claims 1 and 32 (*see* col. 26, line 5);
- the vegetable oil of instant claim 2 (*see* col. 15, lines 53-54]);
- the dimethicone of instant claims 3 and 35 (*see* col. 26, line 38);
- the glycerin of instant claims 5-7 and 37-39 (*see* col. 26, line 4);
- the polyethylene glycol of instant claims 9,10, 41, and 42 (*see* col. 26, lines 6-7);
- the fatty alcohol, stearyl alcohol, of instant claims 9, 11, 41, and 43 (*see* col. 16, line 40);
- the butylene glycol of instant claims 12 and 44 (*see* col. 26, line 5);

- the dispersing agent of instant claim 13 (*see* col. 20, line 27);
- the polydimethylsiloxane of instant claim 14 (*see* col. 20, line 27);
- the skin barrier enhancing agent of instant claims 16 and 46 (*see* col. 17, line 66 – col. 18, line 10);
- the coconut oil of instant claims 17 and 47 (*see* col. 18, line 5);
- the tocopherol of instant claims 19, 20, 49, and 50 (*see* col. 19, lines 25-26);
- the cholesterol of instant claims 21, 22, 51, and 52 (*see* col. 18, line 13);
- the ceramide of instant claims 23 and 56 (*see* col. 17, lines 29);
- the surfactant of instant claims 25 and 53 (*see* col. 25, line 56); and
- the diapers of instant claims 31 and 61 (*see* col. 1, line 7).

Vega, *et. al.* explain that combining the disclosed ingredients into one absorbent product is beneficial because it provides, "...a breathable, protective barrier that keeps body exudates and other irritants from direct contact with the skin yet allows water vapor to pass through." *See* col. 1, lines 22-27.

Vega, *et. al.* do not explicitly teach use of the dispersing agent of instant claim 34 (Dow Corning® 5329). Rather, they teach use of the dispersing agent Dow Corning® 2503 (*see* col. 20, line 50). Because both Dow Corning® 5329 and Dow Corning® 2503 are functionalized dimethicones (*see* Dow Corning® product literature), one of ordinary skill in the art would have been motivated to add either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product. There is a reasonable expectation that the addition of either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product would provide an effective dispersing agent. As such, it would have

been obvious to one of ordinary skill in the art at the time the invention was made to add either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product.

Vega, *et. al.* do not explicitly teach all the percentages recited in instant claims 1, 4, 8, 15, 18, 21, 32, 36, 40, 45, 48, and 51 (or the ratio recited in instant claim 33), however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

The Vega, *et. al.* reference is silent with respect to the (1) phase temperatures of instant claims 1, 28-30, 32 and 58-60; (2) melting point of instant claims 26 and 54; (3) and penetration hardness of instant claims 27 and 55. Applicant's article is the same as the prior art. It contains the same components in the same configuration. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205

USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into an absorbent product, as taught by Vega, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into an absorbent product because they allow for the formation of a breathable, protective barrier that keeps body exudates and other irritants from direct contact with the skin, while allowing water vapor to pass through, as explained by Vega, *et. al.*

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862 ('862). Although the conflicting claims are not identical, they are not patentably distinct from each other because '862 claims a tissue product comprising a moisturizing and lubricating composition comprising an emollient, a humectant, an immobilizing agent, and a compatibilizing agent. *See* claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicant's arguments filed 21 December 2006 have been fully considered but they are not persuasive.

35 USC 112, First Paragraph

Applicants argue that written description support for glucosylceramide is found in original claims 24 and 57. *See* remarks, page 26.

The word "glucosylceramide" is mentioned only in instant claims 24 and 56; it does not appear anywhere else in the original disclosure. A person of ordinary skill in the art is not given any guidance in the disclosure as to how the glucosylceramide is incorporated into the claimed tissue product. No amounts, weights, or percentages are provided; no examples are provided; no mention is made as to how the applicants

intend this compound to be incorporated into a tissue product, as they instantly claim. As such, examiner respectfully submits that instant claim 24 is not supported by an adequate written description in the instant disclosure.

*

35 USC 103

1. Applicants argue that, "...Vega, et al. fail to teach or suggest a composition comprising from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. *See* remarks, pp 28-29.

Examiner respectfully submits that applicants are claiming a very broad range, i.e. 1% - 40% by weight. Applicants show no criticality of the claimed range.

Applicants direct the record to paragraph 66 of the instant application to show, "...the compatibility of the moisturizing and lubricating compositions of the present invention is important for the processability and stability of the compositions." *See* remarks, page 29. However, the cited language is directed to the compatibility of compositions in the mixing process, not a particular concentration range of compatibilizing agent; it does not specifically address why the broad range of 1%-40% of compatibilizing agent is critical.

2. Applicants argue that, "[t]here is...no disclosure of using propylene glycol, butylenes glycol, or low molecular weight polyethylene glycols as compatibilizing agents, or of the need for compatibilizing agents generally. *See* remarks, page 30.

Examiner respectfully submits that processing of compositions (i.e. the proposed benefit of compatibilizing agents) is not essential to a determination of patentability of

the composition disclosed in the claim. As explained by the court in *In re Thorpe et. al.* (CAFC 1985) 779 F2d 695, "A claim to a composition defined by reference to the process by which it is produced, is not limited to compositions produced by the process recited in the claim." It should be noted that processing of compositions is not being claimed; only the agents are being claimed.

Furthermore, the description of "compatibilizing agent" at paragraph 65 of the instant specification recites propylene glycol and low molecular weight polyethylene glycols as appropriate compatibilizing agents, both of which are disclosed in the Vega, et al. reference (*see* col. 26, lines 5-7).

3. Applicants argue that, "...claim 10 requires the polyethylene glycol to be selected from the group consisting of PEG 1000, PEG 3350, PEG 6000, PEG 8000, and PEG 10,000. Vega, et al. fail to teach or suggest compositions comprising any of these immobilizing agents. *See* remarks, page 31.

Examiner respectfully submits that high molecular weight PEGs are disclosed in U.S. Patent No. 4,556,660 (*see* col. 13, lines 6-11), which is incorporated into Vega, et al. by reference (*see* col. 26, line 64).

*

Pages 32-33 of the remarks address claims 32, 33, and 36-61; all issues have been addressed in the responses above for claims 1-31.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***

HUMERA N SHEIKH
PRIMARY EXAMINER